THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID H. GELFAND,
SUSANNE STOFFEL
and RANDALL SAIKI

Appeal No. 95-0024
Application 07/873,897[1]

HEARING: May 7, 1997

Before WILLIAM F. SMITH, GRON and WALTZ, Administrative Patent Judges.

GRON, Administrative Patent Judge.

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[1] Application for patent filed April 24, 1992. According to applicants, this application is a continuation of Application 07/387,003, filed July 28, 1989, abandoned; which is a divisional of Application 07/143,441, filed January 12, 1988, abandoned; which is a continuation-in-part of Application 07/063,509, filed June 17, 1987, now U.S. Patent 4,889,818, granted December 28, 1989; which is a continuation-in-part of Application 06/899,241, filed August 22, 1986, abandoned.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal under 35 U.S.C. § 134 of an examiner's final rejections of Claims 1, 35-39, and 53-62. The examiner has allowed Claims 40 and 41, the only other claims still pending in this application. We reverse all the examiner's rejections.

Introduction

Claims 1, 35-39, and 53-62 stand finally rejected under 35 U.S.C. § 112, first paragraph, as being broader in scope than the enabling disclosure. Claims 1, 35-39, and 53-59 stand finally rejected under 35 U.S.C. § 102(a) as being anticipated by the MBR Product Information Sheet (MBR), "DNA Polymerase (*Thermus aquaticus*)," published June 8, 1987. Claims 60-62 stand finally rejected under 35 U.S.C. § 103 as being unpatentable in view of the same MBR disclosure. Claims 1, 35-39, 53-59 and 62 stand rejected under 35 U.S.C. § 103 as being unpatentable in view of the combined teachings of Kaledin et al. (Kaledin'80), "Isolation and Properties of DNA Polymerase From Extremely Thermophilic Bacterium *Thermus aquaticus* YT1," Biokhimiya, Vol. 45, No. 4, pp. 644-651 (1980) and Goff et al. (Goff), U.S. 4,943,531, patented July 24, 1990 (prior art under 35 U.S.C. § 102(e) based

on the May 6, 1985, filing date of Application 06/731,128), optionally further in view of Feller et al. (Feller), U.S. 4,409,200, patented October 11, 1983, or Spiegelman, U.S. 4,379,839, patented April 12, 1983. Claims 60 and 61 stand finally rejected under 35 U.S.C. § 103 as being unpatentable in view of the combined teachings of Kaledin '80, Goff, and optionally Feller or Spiegelman, further in view of Kaledin et al. (Kaledin'81), "Isolation and Properties of DNA Polymerase from the Extremely Thermophilic Bacterium *Thermus flavus*," Biokhimiya, Vol. 46, No. 9, pp. 1576-1584 (1981). Representative Claims 1 and 62 are reproduced below.

> 1. A stable enzyme composition comprising a purified thermostable nucleic acid polymerase enzyme in a buffer that comprises one or more non-ionic polymeric detergents.
>
> 62. A reaction mixture that comprises nucleoside-5'-triphosphates, oligonucleotide primers, a buffer in which primer extension by a polymerase can occur, and an aliquot of a stable enzyme composition comprising a purified thermostable nucleic acid polymerase enzyme in a buffer and further comprising one or more nonionic polymeric detergents.

Discussion

We have carefully and comprehensively considered the claims on appeal and the supporting specification; Appellants' Brief and

Reply Brief; the Examiner's Answer and Supplemental Answer; the Declarations Under 37 C.F.R. § 1.131 of David H. Gelfand, Susanne Stoffel and Randall Saiki, dated April 21, 1992 and January 6, 1993, and supporting documents; the Declarations Under 37 C.F.R. § 1.132 of James Akers, dated April 22, 1992, and David H. Gelfand, dated April 21, 1992; the article by Wu et al. (Wu), "On the Stimulation of Viral DNA Polymerase Activity by Nonionic Detergent," Biochemistry, Vol. 14, No. 4, pp. 789-795 (1975); and various technical publications submitted by applicants which describe storage buffers suitable for DNA polymerase. Having considered the above and all other evidence of record for and against patentability, we reverse every one of the appealed rejections, essentially for reasons stated in Appellants' Brief (Paper No. 30) and Reply Brief (Paper No. 32). Hereafter, we limit our remarks to the more significant errors.

Discussion

The examiner has the initial burden under 35 U.S.C. § 112, first paragraph, to explain why he doubts that appellants' specification would have enabled persons skilled in the art to make and use the full scope of the subject matter claimed.

See In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971):

> . . . [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Here, we find that the examiner proffers a high level of unpredictability in the art and the commensurate need for experimentation as the basis for his doubts that appellants' specification would have been enabling. While Marzocchi, 439 F.2d at 223-24, 169 USPQ at 369-70, acknowledges that unpredictability alone may create sufficient doubt that broad statements in the specification would have enabled the full scope of the invention claimed, the asserted unpredictability must be substantiated by evidence or convincing argument that the scope of objective enablement in appellants' specification is in fact insufficient to support the scope of protection sought. Id. at 224, 169 USPQ at 370 (emphasis added):

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting

> disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Appellants argue that while their disclosure may require persons skilled in the art to perform some experimentation to achieve success, the evidence of record does not show that the amount of experimentation appellants' disclosure requires is undue. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)("That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'") We agree. We find that the amount and kind of experimentation appellants require persons skilled in the art to perform to confirm stabilization of specific thermostable enzymes by particular nonionic polymeric detergents is well within the ordinary skill of the artisan in the pertinent field. We say "confirm" because appellants' specification provides the guidance and direction necessary for the skilled artisan reasonably to expect success.

The examiner points to prior art teachings and appellants' own disclosure that enzymatic activity varies substantially according to the environment, i.e. pH, the kind of buffer, the presence or absence of gelatin, the kinds, amounts, and numbers

of nonionic surfactants employed, etc.. However, Marzocchi, at 223, 169 USPQ at 369, states that "a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling."

Appellants do not deny that enzyme activity varies with the environment and appear to concede that the information to which the examiner points is well-known in the art. Nevertheless, we agree with appellants that their specification, the declarations of record, the attachments thereto, and the cited prior art and publications corroborate the statements in appellants' specification that the enzymatic activity of purified thermostable nucleic acid polymerase enzyme is in fact stabilized by nonionic polymeric detergents, all other suspected environmental variables having been either eliminated as variables or held constant. While the examiner's explanation of the basis for the rejection prima facie appears to have had some merit, we hold that he clearly erred in selectively and incompletely considering appellants' declaration and other rebuttal evidence and granted far too little weight to the evidence appellants submitted in response.

We hold that the examiner clearly erred in finding the Declarations under 37 CFR § 1.131 of David H. Gelfand, Susanne Stoffel and Randall Saiki insufficient to antedate the June 8, 1987, publication date of the MBR Product Information Sheet (MBR), "DNA Polymerase (*Thermus aquaticus*)." In our view, the declarations establish that applicants reduced the claimed invention to practice prior to June 8, 1987. Appellants claim a stable enzyme composition comprising a purified thermostable nucleic acid polymerase enzyme in a buffer that "comprises one or more non-ionic polymeric detergents" (Claim 1). We find no evidence of record to support the examiner's apparent conclusion that the claimed composition comprising one enzyme-stabilizing nonionic polymeric detergent is patentably distinct from the claimed composition comprising two enzyme-stabilizing nonionic polymeric detergents. Accordingly, we hold that the examiner erred in concluding that applicants' reduction of a thermal stable nucleic acid polymerase enzyme composition in a buffer comprising two nonionic polymeric detergents to practice prior to June 8, 1987, is insufficient to show reduction to practice of the claimed invention prior to publication of the MBR disclosure under 37 CFR § 1.131.

In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1998), instructs at 1074, 5 USPQ2d at 1598:

> The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. . . . It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.

To meet this burden, the examiner cannot pick and choose to apply only those portions of the prior art which support the proposition that appellants' claimed invention is unpatentable. This is impermissible hindsight. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." Id. at 1075, 5 USPQ2d at 1600. The examiner's limited reading of Goff's teachings is impermissible. "It is axiomatic that a reference must be considered in its entirety." In re Fracalossi, 681 F.2d 792, 794 n.1, 215 USPQ 569, 570 n.1 (CCPA 1982). "It is well settled that a prior art reference is relevant for all that it teaches to those of ordinary skill in the art." In re Fritch, 972 F.2d 1260, 1264, 23 USPQ2d 1780, 1782 (Fed. Cir. 1992).

Compare Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448, 230 USPQ 416, 420 (Fed. Cir. 1986):

> The district court improperly viewed an isolated line in Caddell in light of the teaching of the '814 patent to hold for obviousness. This is improper hindsight analysis.
>
> The district court also failed to consider the Caddell reference in its entirety and thereby ignored those portions of the reference that argued against obviousness.

After seemingly having established a prima facie case of unpatentability based on very select prior art teachings, the examiner effectively shut his eyes to the prior art teachings favoring patentability. The examiner's error in so doing is compounded because, rather than stepping back and evaluating patentability anew based on newly submitted evidence, he vigorously attacked very specific elements of appellants' rebuttal evidence without considering any of its strengths or all the evidence favoring patentability against all the evidence to the contrary. Since the PTO has the initial burden of establishing unpatentability and must weigh all the evidence supporting unpatentability rejections against all the evidence presented favoring patentability, the examiner's failure to do so in this case constitutes reversible error.

Limited readings of applied prior art teachings and applicants' showings and other evidence in rebuttal in a few cases may have a "chilling effect" on the manner in which patent applications are prosecuted by patent applicants in the PTO in the future. This appeal is well taken.

Conclusion

We reverse all the examiner's rejections.

REVERSED

William F. Smith

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